NFPA
The Food Safety People

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ASSOCIATION

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September 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; 64 Federal Register 47845.

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the principal scientific trade association representing the $460 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management.

NFPA's scientists, government affairs, regulatory, and communications experts, provide assistance to member companies and work to ensure that laws and regulations governing the food industry have a sound scientific foundation.

NFPA offers the following comments on CFSAN program priorities.

1. **With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?**

CFSAN has clearly failed in its effort to assure the safety of raw juice with the juice HACCP proposal. Efforts to wash away contamination can never be 100% effective thereby leaving a portion of the population at risk. Research confirms that pathogens such as *E. coli* O157:H7, *Salmonella,* and *Cryptosporidium* can survive in raw juice. The recent outbreak of *Salmonella* spp. in raw orange juice confirmed FDA's "interim HACCP" policy does not work without the incorporation of pasteurization or an equivalent kill step sufficient to destroy pathogenic microorganisms which may be present in the juice.

We request the Agency move expeditiously to enforce existing Good Manufacturing Practice regulations at 21 CFR Part 110.80(a)(2) "raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans or they shall be pasteurized or

98N-0359 C33

otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act." Clearly CFSAN should respond as it did when requiring the pasteurization of all milk in interstate commerce and adopt a requirement for pasteurization or an equivalent kill step (5-log reduction) for all juices in interstate commerce. This question has been before the Agency since 1996 and clearly the time for resolution is long overdue. NFPA has filed several sets of comments and communicated these concerns to CFSAN. Political dealings should come after rather than before food safety concerns.

2. Within the 10 program areas identified previously, what specific activities do you believe should be top priorities for CFSAN and why?

NFPA strongly believes that food safety issues should be the number one priority of CFSAN. However, not all areas of the Food Safety Initiative (FSI) deserve equal attention. Our top priorities in the FSI are education, research and risk assessment, followed by surveillance and outbreak response. Specific comments on these areas are noted below.

- Food Safety Initiative

Imports:

Pursue action on USTR memo 99-52, June 21, 1999, which states that "The U.S. and EU have agreed to pursue the establishment of an early warning system on food safety. The U.S. and the EU are exchanging information on their respective legislative and regulatory initiatives in food safety, which could relate to transatlantic trade. Both sides are also exchanging information on their systems for a rapid alert system to inform other countries of food safety problems. Also, the two sides are pursuing a formal arrangement to cooperate in the exchange of information and education in the risk assessment area." The recent dioxin contamination incident in Belgium underscores the need for rapid response to assure that all parties take appropriate remedial actions as quickly as possible.

While there is no evidence that imports pose a greater risk than domestic products, numerous reports have revealed deficiencies in the current system and NFPA believes that imported food safety deserves more attention. However, FDA should focus on how it can most effectively use its current authorities to address the issue, rather than drafting new laws that may not be needed. A first step is to work with industry to outline the problems that need to be addressed, listing approaches that could be used to address the problems and then identifying whether new laws or regulations are needed.

HACCP:

The juice HACCP proposal should be reevaluated in light of current science and amended to require pasteurization or an equivalent process in raw juice to achieve at least a 5-log reduction in microorganisms of public health concern. We see no need to expand HACCP to other products at this time. However, we support FDA's efforts to address the use of HACCP voluntarily at retail.

Produce:

FDA should continue its efforts to educate domestic and international producers with respect to Good Agricultural Practices and Good Manufacturing Practices.

Additional Prevention Efforts:

FDA should continue to give high priority to the Food Code, updating it as new information becomes available, and working with state and local agencies to implement its provisions, thus promoting uniformity across the US.

Domestic Surveillance and Outbreak Response:

Cooperation with CDC and state officials in identifying food-related illnesses and tracking down the source should continue to be a priority for CFSAN. In addition, efforts should be focused on identifying trends and targeting prevention strategies. Resources should be devoted to analyzing data and making it publicly available in a timely manner so industry and others can use the information to target research and control efforts. We also encourage FDA to give priority to issuing for public comment guidance on foodborne outbreak response and coordination; it is important that industry have a role in identifying how the industry and investigating agencies should work together to coordinate investigations and rapidly remove food products that might cause adverse public health effects.

Finally, we urge FDA to give priority to working with CDC to implement the *Listeria monocytogenes* case control study. This study will provide important data needed for the ongoing risk assessment on this organism.

Research:

NFPA strongly supports research that will enhance our understanding of how foods become contaminated with pathogens, as well as research that leads to new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs. We also support research aimed at detecting pathogens in foods, because these methods are the tools we need to understand the ecology and control of foodborne

pathogens. In addition, risk assessments underway will identify data gaps that will require research to fill. This should be given a high priority.

Risk Assessment:

The risk assessment focus should be expanded to encompass all aspects of risk analysis: risk assessment, risk management and risk communication. The risk assessments currently underway will point out the need for additional research. Once additional data become available, risk assessments will need to be updated. Thus this will be an evolving and continuing process, and risk assessments in new areas will be needed. Moreover, given the need for transparency in risk assessment and risk management, risk communication will take on a heightened importance. NFPA believes that more resources will need to be devoted to the risk analysis area in the future.

Education:

Food safety education remains the least expensive, yet most effective, weapon against foodborne disease. Education at every step along the food chain – from food producers, to handlers, to those who prepare and serve foods in restaurants or in the home – is vital, so that the safety of foods is maintained all the way to the table. Food safety education in the schools and for high-risk individuals offers the best opportunity to make the public aware that there is always some risk and that consumers must do their part to ensure the food they eat is safe. We support efforts such as FDA's Outreach and Information Center, an important resource to make food safety information available to consumers. A consumer-oriented food safety website would also effectively reach certain segments of the population.

We also strongly support the addition of a guideline in the 2000 Dietary Guidelines for Americans (currently under revision) emphasizing the importance of consumers practicing food safety procedures.

CFSAN should expand efforts to educate the public on the steps and methods FDA uses to assure the safety of genetically modified foods. FDA should use public forums to further deepen public confidence in the current regulatory approval process for these foods.

- Premarket Review of Food Ingredients

CFSAN should issue a final rule implementing its proposal to replace the petition process for affirming a substance as Generally Recognized as Safe (GRAS) with a GRAS notification procedure (Docket No. 97N-0103).

CFSAN should expedite review of a petition to approve the use of irradiation for a number of ready-to-eat products. The petition, which covers a variety of ready-

to-eat meat, poultry, fruits and vegetable products, was filed with FDA on August 23, 1999 by the Food Irradiation Coalition. This "cold pasteurization" process holds the promise of helping to reduce significantly the risk of foodborne illness in this country.

In a June 4, 1999 letter to Dr. Jane Henney, Commissioner, FDA and Mr. Tom Billy, Administrator, FSIS, the NFPA joined six other food industry trade associations in requesting the agencies make final the proposed regulations reforming review procedures for food additives requiring both FDA and FSIS approval. The proposed rules (60 Federal Register 67459 and 67490) were published almost four years ago (December 29, 1995). Finalizing these rules would eliminate the need for a separate FSIS rule to allow the use of FDA-approved substances in meat and poultry products.

- Nutrition, Health Claims and Labeling

NFPA believes that, in this program area, CFSAN should concentrate effort on related subjects dealing with expression of health claims and nutrient content claims on food labels. Working on several related subjects simultaneously can take advantage of critical intellectual mass, and will ensure greater consistency in outcome of these policy topics. As many of these subjects will necessitate new thinking because of the court decision in *Pearson v. Shalala*, NFPA feels it is timely to link these projects to the development of an implementation strategy for *Pearson*, which is a CFSAN mid-term 1999 goal in the dietary supplements program. In the same vein, NFPA believes that work assigned to the "B" list in 1999 should be subject to elevation to the "A" list in 2000. Consequently, NFPA recommends that FDA assign all the following subjects to the "A" priority list for the Nutrition, Health Claims and Labeling program:

1. In response to citizen petitions 94P-0390 [NFPA petition] and 95P-0241, publish a final rule amending the regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products.
2. Develop a strategy regarding the most appropriate scientific and regulatory framework of structure/function claims on conventional foods.
3. Refine the guidelines issued concerning criteria for filing and decision making on nutrient content and health claims based on authoritative statements, which implements sections 303 and 304 of FDAMA.

Food Standards

In addition to these priorities, NFPA believes that CFSAN should assign to food standards of identity some place on its prioritization scheme. Maintenance of the regulatory framework for food standards is important for both consumers and the food industry, yet food standards were deemed not to be a priority activity for CFSAN in 1999. NFPA objects to this glaring lack of attention, and we reiterate

herein the points we expressed in our written comments, submitted in 1998, on the 1999 priority setting activity:

A high priority should be placed by CFSAN on the continued maintenance and administration of the food standards program. A number of the existing standards presently serve as barriers to the utilization of new technologies and ingredients to improve existing products. This, in turn, has made it difficult for the U.S. to promote an effective U.S. position at recent Codex Committee meetings, in light of the outmoded standards now in place. As a result, petitions have been filed in several important product categories to effect needed amendments that recognize advances in food technology and the need for flexibility. FDA must provide necessary resources and assign priority to this important function.

As a case in point, on May 13, 1988, NFPA petitioned the Agency to amend the standard of identity for canned salmon (21 CFR §160.170) to permit the production of a "skinless, boneless" style of salmon pack. The petition was amended on June 12, 1989 (Docket No. 88P-0190/CP2) and accepted for filing. Several manufacturers were issued "Temporary Marketing Permits" to pack the product while the petition was under consideration. The petition has never been acted on by the Agency, although it has been assigned to at least four different CFSAN staff during the subsequent nine-year interval. This spring we were contacted by an Agency official seeking to "clear the books on several old petitions" and asking that we withdraw the petition. However, by withdrawing the petition NFPA would negate any Temporary Marketing Permits currently in effect and preclude any future production of an otherwise acceptable food product. NFPA determined the petition should remain in place.

NFPA believes it is appropriate for FDA to assign to the "B" list the completion of rulemaking on all pending petitions related to food standards of identity.

Prevention of Economic Fraud

CFSAN should make issues related to economic fraud a priority for attention. While clearly not as important as food safety or activities to harmonize global rules, the agency must maintain a recognized presence in the area of enforcement to assure that consumers are not being cheated, and that the reputable food industry is not at a disadvantage for complying with the law and regulations. Ensuring consumer confidence in the food supply through prevention of economic fraud is a necessary corollary of consumer protection through strong food safety activities. Individuals and companies engaged in fraudulent activities are just as likely to have little regard for the welfare and safety of the public, and should not be allowed to operate. FDA has an obligation to enforce the existing statutory provisions and to continue to pursue and prosecute fraudulent activities.

- Dietary Supplements

NFPA supports CFSAN's recognition that the *Pearson* court decision is a key issue related to dietary supplements claims, as reflected by the mid-1999 assignment of *Pearson* strategy to the "A" list of priorities. In conjunction with related subject matter in the Nutrition, Health Claims and Labeling program, NFPA believes that, for the year 2000, FDA should maintain Pearson activity on the "A" list for dietary supplements, and complete the implementation of policy changes necessitated by this key judicial decision.

- Chemical and Other Contaminants

CFSAN should initiate action to establish an action level of 50μg/kg for patulin in single strength apple juice or apple juice from concentrate. NFPA has supported such action since 1996 and this was listed as an agency priority for 1999. The FDA Food Advisory Committee endorsed establishment of a 50μg/kg patulin level at its June 1999 meeting.

- Cosmetics

This area is of minimal interest compared to food safety issues.

- Enhancing the Science Base

CFSAN must maintain and enhance its science capabilities to assure that agency decisions are based on sound science and risk assessment.

- Federal/State/local collaborations

CFSAN should continue support for uniformity of regulatory enforcement. There is a need for continued agency participation in State regulatory training courses and with State regulatory officials through the Association of Food and Drug Officials.

- International

CFSAN should continue to place a high priority on international activities including participation in Codex Alimentarius. More detailed comments concerning international activities are provided in NFPA's response to question 4.

- Human Resources

CFSAN should identify scientific staffing needs for the near and long-term. The Agency should identify critical staff positions which will be vacated through retirement and prepare by hiring individuals capable of moving into that position.

Within two years the Agency is scheduled to relocate. CFSAN needs a clear plan on how that move will be handled to assure that staff will be available to provide continuous support for food related operations.

3. **FDA needs to ensure that its research programs provide the scientific information upon which regulatory decisions are made. In CFSAN, what do you believe should be the highest priority areas for conducting research?**

Research was discussed earlier as a component of the Food Safety Initiative. NFPA suggests that the highest priority for research should be to provide information to fill the gaps in data needed for risk assessments, as risk assessments must form the foundation for making regulatory decisions.

4. **Because so much of our nation's food supply is either imported or exported, what do you believe should be the highest priority international activities? Please identify specific activities in your answer.**

NFPA urges CFSAN to prioritize efforts to improve international food safety standards through Codex Alimentarius. Since 1962, Codex countries (165) have been developing model standards, guidelines and codes of practice related to the safe and hygienic production of foods. This effort is critical to enhance food safety standards globally as well as to facilitate trade. CFSAN must strengthen its role in Codex and increase transparency in the Codex process, dedicate additional resources and provide more training for the delegates.

CFSAN's 1999 Program Priorities "A" List recognized the importance of an affirmative action agenda for international activities including participation in Codex. CFSAN also recognized the importance of equivalence criteria and determinations and developing Agency policy toward export certification. These program priorities are even more appropriate for 2000. Political developments related to trade with the EU and perceived (and real) food safety issues regarding imported food products in the past year demand an aggressive CFSAN international agenda. New U.S. leadership of Codex Alimentarius provides an opportunity to assure that Codex standards are based on sound science and risk assessment and that political interests do not compromise food safety. Codex provides an important forum to harmonize equivalency criteria and food certification. NFPA urges CFSAN's continued strong participation in the Codex process and other similar activities that strengthen international food safety. These activities have resulted in increased food safety standards worldwide, and will enhance the safety and quality of U.S. food imports.

Recognition of equivalence between nations will ultimately elevate food safety standards internationally while simultaneously minimizing resource intensive

procedures. FDA should issue a final rule implementing its proposed draft criteria for the determination of equivalence published in 1997.

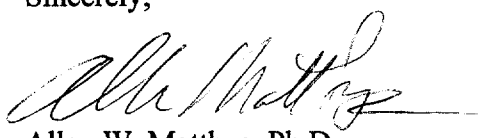
Product certification, although broadly accepted in international trade, may be used inappropriately to discourage imports and protect domestic industry. Harmonization of international standards and increased transparency is critical. Clear rules on obtaining export certification for U.S. authorities is equally important in order to facilitate trade while providing appropriate assurance of food safety to our trading partners.

For 2000, NFPA encourages FDA to work towards harmonization of standards with both our NAFTA partners. Increased trade with Mexico in recent years highlights the need for the three countries to work together through NAFTA and Codex towards the common goal of facilitating cross border trade of the highest quality food products. In response to technical trade barriers resulting from certification problems, a working group was formed within the NAFTA SPS committee to explore harmonized certification standards. NFPA encourages FDA to seek similar opportunities.

FDA should take a more proactive stance to review and comment on notifications from the World Trade Organization (WTO) with respect to Sanitary Phytosanitary (SPS) and Technical Barrier to Trade (TBT) issues to better assist USDA in identifying potential barriers to trade. Identification of trade barriers is critical in country-to-country negotiations. Interagency cooperation is important to capitalize on an opportunity to correct inappropriate food standards before trade disruptions or public health issues result.

Thank you for providing this opportunity to comment on CFSAN priorities for the coming year.

Sincerely,



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